UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. PETER J. BADDICK, III., DO., Defendant.	Civil Action No. 3:22-cv-00512-KM

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS THE COMPLAINT

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Peter J. Baddick, III, DO. (hereinafter "Dr. Baddick" or "Defendant") submits this memorandum of law in support of his Motion to Dismiss the Complaint of the United States of America (hereinafter "Plaintiff" or "government") pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure and for attorneys' fees and expenses pursuant to the Court's inherent authority to police the conduct of the litigants before it.

INTRODUCTION

Despite rampant False Claims Act (FCA) filings in the healthcare space, one would be hard-pressed to identify a more spurious pleading than the case at bar, in which the government pries into the exam room of a medical professional to second-guess his treatment of two patients over a 27-year distinguished career. Insys was an outlaw company, no doubt, but the government's attempt to conceal its pleading deficiencies by painting Dr. Baddick with the Subsys tarbrush fails miserably: he never took a dime from the company to prescribe Subsys, the product at issue. And while Insys and its executives broke the law by promoting Subsys for "off label" uses, the law is settled that physicians are not only permitted to prescribe "off-label," they are **encouraged** to do so by the FDA for the advancement of medical science and patient care. In short, contrary to the government's conclusory and vague allegations, Dr. Baddick did not violate any law, let alone the FCA, by prescribing Subsys to non-cancer patients "off label," i.e., a legitimate medical purpose

expressly contemplated by the Food & Drug Administration when it approved the drug in the first place.[1]

Nonetheless, the government goes so far as to allege that Dr. Baddick acted no differently than a street-corner drug dealer. See Compl. ¶ 71; 73 (alleging Dr. Baddick violated the CSA by prescribing "under circumstances that were not for a legitimate medical purpose in the usual course of professional practice"). Indeed, the government's conclusory allegation that Dr. Baddick had become a drug pusher and/or a drug dealer is not grounded in facts and/or in law, and the government's bald claims are supported by **no facts** whatsoever, let alone the specific and articulable facts required by Rule 9(b). Indeed, despite myriad variations, the cornerstone of each of the government's claims is that Dr. Baddick's prescriptions were "not issued for a legitimate medical purpose." Compl. ¶¶ 159 & 163 (alleging two different theories: lack of "medically accepted indication" and "valid" prescriptions); ¶¶167 & 171 (alleging third theory: "not medically necessary prescription drugs"). At no point in its meandering Complaint, however, does the government articulate why, precisely, it contends the prescriptions at issue were not

[1] Indeed, the Subsys prior authorization form—on which payors relied to approve or reject payment for Subsys—expressly contemplates the use of Subsys to treat at least 10 other off-label uses, including chronic pain, dysphagia, RSD upper limb, degeneration of cervical intervertebral disc, and postlaminectomy syndrome. See **Exhibit A,** Declaration of Conor R. McCabe in Support of Defendant's Motion to Dismiss ("McCabe Decl."), Ex. 1.

issued for a legitimate medical purpose. What's more concerning, the government deliberately omits to mention that its Medicare and TRICARE benefit managers authorized reimbursement for the very claims at issue before the medication was dispensed or that at any point following reimbursement, they reversed their reimbursement for the said claims.

Further, the government—not a bounty-seeking relator—deliberately omits and misleadingly cites portions of the medical record in a shameful attempt to "artfully" craft a case where none exists. Specifically, the Court need look no further than Paragraph 124 to appreciate the degree to which the government has attempted to deceive. The government alleges that "[t]he medical history completed by A.P. at the initial visit did not indicate that A.P. was or had been diagnosed with cancer." Compl. ¶ 124. Contrary to the government's deliberate omissions, the patient's form—which the government conspicuously fails to attach to the Complaint—specifically states, "Cancer Other Type: follow-up for multiple myeloma." See McCabe Decl. Ex. 2. That the government nowhere mentions, let alone directly addresses this fact head-on, smacks of prosecutorial misconduct and, at a minimum, dishonesty and lack of candor to the tribunal. The Court's review should be guided accordingly.[2]

[2] On August 12, 2022, counsel for Dr. Baddick had notified the government of the erroneous allegation and advised the government to amend its Complaint; however, the government refused to do so. See McCabe Decl. Ex. 3.

Finally, in addition to the lack of substantive merit, this case is time-barred. Nonetheless, the government attempted to revive its claims through a purported "tolling" agreement that was never signed by Dr. Baddick, only prior counsel. Notably, the plain language of that so-called "tolling" agreement, demonstrates that the agreement lacks consideration and is therefore unenforceable. Specifically, the tolling agreement signed for the first time in 2021 outlines that in exchange for tolling the limitations period, the government agrees not to bring any claims against Dr. Baddick in 2020. See McCabe Decl. Ex. 4.

Accordingly, for all of the foregoing reasons, the Complaint should be dismissed with prejudice and Dr. Baddick awarded his costs and attorneys' fees associated with defending this frivolous and unmeritorious action. See Doering v. Union Cnty. Bd. of Chosen Freeholders, 857 F.2d 191 (3d Cir. 1988) ("[b]y awarding attorney fees to prevailing defendants in effort to discourage plaintiffs from bringing baseless actions or making frivolous motions, Rule 11's primary purpose is not wholesale fee shifting but rather correction of litigation abuse).

STATEMENT OF FACTS

On April 6, 2022, months after the statute of limitations had expired, the government filed the instant Complaint against Dr. Baddick. The government's Complaint alleges that Dr. Baddick, a licensed physician and surgeon, has been authorized by the DEA to prescribe controlled substances since 1996. Compl. at ¶¶

9,11. At all relevant times, Dr. Baddick was also enrolled in the Food and Drug Administration's ("FDA") Transmucosal Immediate Release Fentanyl ("TIRF") Risk Evaluation and Mitigation Strategy ("REMS") Access Program, a mandatory requirement for all prescribers of fentanyl products such as Subsys, a pain medication approved by the FDA to treat breakthrough pain in adult cancer patients who are opioid tolerant. Id. at ¶¶ 60, 63, 66.

The Complaint further alleges that Dr. Baddick attended speaker program events where Subsys prescribers, who were paid by Insys, the manufacturer of Subsys, gave presentations on Subsys. Id. at ¶¶ 61,62. Importantly, the Complaint does not allege that Dr. Baddick was a paid speaker in the program, or that he received any financial compensation from Insys and/or that he was motivated, financially or otherwise, to prescribe Subsys. See id.

Instead, the Complaint alleges that Dr. Baddick wrote a handful of Subsys prescriptions, over the course of several months in 2015, to two of his patients who suffered from several debilitating medical conditions. Id. at ¶¶74-115, ¶¶117-155. Specifically, Dr. Baddick wrote a total of 11 Subsys prescriptions for Patient M.G. who he had been treating since 2006. Id. at ¶¶ 75, 115. Indeed, the Complaint highlights that patient M.G. suffered from back pain for 25 years, and prior to April 2015, she received 23 injections to manager her pain. Id. at ¶ 76. In addition to back pain, patient M.G. was also diagnosed with chronic pain, chronic pain syndrome,

herniated nucleus pulposus lumbar, degeneration of cervical and cervicothoracic intervertebral discs, gastroesophageal reflux disease, among other ailments. Id. at ¶¶ 76, 77. As a result, Dr. Baddick began prescribing Subsys to patient M.G. on April 1, 2015. Id. at ¶ 78. While prescribing Subsys to patient M.G., Dr. Baddick had regular follow-up visits with the patient and meticulously documented the medication checks, M.G's progress and ongoing health complaints, as well as her concerns that she was having a reaction to Subsys. Id. at ¶¶ 80-106. To that end, when Dr. Baddick learned that patient M.G. began experiencing opioid withdrawal, he immediately discontinued her Subsys prescriptions and continued regular follow-up visits. Id. at ¶¶111-114.

Despite providing a detailed description of the exceptional medical care Dr. Baddick provided to patient M.G. and outlining a number of debilitating conditions that M.G. was suffering from that required pain control, the government then inexplicably alleges that Dr. Baddick prescribed Subsys to M.G. without a legitimate medical purpose and outside the usual course of professional practice, which presumably made the Subsys prescriptions Dr. Baddick wrote for M.G. invalid, under Pennsylvania law. Id. at ¶ 116.

The Complaint then recites similar facts as to patient A.P. who Dr. Baddick treated for cancer, sarcoidosis, endometriosis, Raynaud's phenomenon, and chronic pain syndrome. Id. at ¶ 125. Patient A.P. was a new patient who was complaining of

chronic pain despite being treated with Oxycodone. Id. at ¶¶ 124, 126. She first saw Dr. Baddick in June of 2015, allegedly on a recommendation from an Insys sales representative she met through a mutual acquaintances. Id. at ¶¶ 118, 123. The Complaint does not allege that Dr. Baddick knew this sales representative, and/or that he was aware that patient A.P. made the appointment with him on the recommendation of the sales representative. See id.

Importantly, while A.P. suffered from a number of conditions associated with chronic pain, as outlined in the Complaint, at A.P.'s initial visit, she advised Dr. Baddick that she was suffering from multiple myeloma, and A.P. indicated on her initial intake form that one of the reasons for her visit was a "follow up for multiple myeloma." See McCabe Decl. Ex. 2. However, the government's Complaint falsely alleges that "[t]he medical history completed by A.P. at the initial visit did not indicate that A.P. was or had been diagnosed with cancer." Id. at ¶ 124. This blatant falsity is contrary to A.P.'s medical records, and should be given no weight.

Following patient A.P.'s initial visit and examination, Dr. Baddick advised her to discontinue Oxycodone and prescribed Subsys. Id. at ¶¶ 126, 127. For the next several months, Dr. Baddick continued monitoring patient A.P. on a regular basis by having monthly follow-up visits which included medication checks, and urine (drug) screens. Id. at ¶¶ 133-148, 154. Several months after patient A.P. was first prescribed Subsys, she informed Dr. Baddick that she was no longer taking Subsys, at which

point he immediately discontinued her Subsys prescriptions. Id. at ¶ 151.

Without any facts and/or explanations to substantiate the conclusory allegation, the Complaint then arbitrarily alleges that Subsys was not indicated by A.P.'s diagnoses, and that Dr. Baddick prescribed Subsys to A.P. without a legitimate medical purpose and outside the usual course of professional practice, thereby rendering the prescriptions invalid under Pennsylvania law. Id. at ¶ 156. Indeed, the Complaint materially misrepresents the fact that Dr. Baddick was advised by A.P. that she suffered from cancer, as A.P.'s medical history form contained cancer as one of her ailments. Moreover, the Complaint fails to allege any facts that could possibly demonstrate why Dr. Baddick's professional decision making was improper and fell outside the perimeter of the ordinary course of his medical practice.

In sum, not only are portions of the Complaint materially false but the Complaint is lacking any factual allegations as to why Subsys was not appropriate for treatment of M.G. and A.P.'s ailments, and/or why off-label prescribing, a commonplace prescribing practice, automatically renders the prescriptions invalid and medically unnecessary, and it does so despite specifically outlining that the government payors authorized the coverage for Dr. Baddick's Subsys prescriptions

after receiving documentation, "signed by Dr. Baddick,"[3] that clearly indicated the conditions for which Subsys was being prescribed to M.G. and A.P.

Specifically, the Complaint alleges that on April 2, 2015, Dr. Baddick signed an Insys Reimbursement Center and Patient Authorization & Referral Form indicating that M.G. had been diagnosed with degeneration of cervical intervertebral disc/degeneration of cervicothoracic intervertebral disc, chronic pain and chronic pain syndrome. Id. at ¶ 77 The form did not indicate that M.G. was diagnosed with breakthrough cancer pain See id. Likewise, the Complaint alleges that on June 11, 2015, Dr. Baddick signed the Insys Reimbursement Center and Patient Authorization & Referral Form indicating that A.P. had been diagnosed with cancer, sarcoidosis, chronic pain, chronic pain syndrome, and endometriosis, the form did not indicate that A.P. was diagnosed with breakthrough cancer pain. See id. at ¶ 128. Following the submission of the preauthorization forms to the government payors, the payors determined that Dr. Baddick's Subsys prescriptions were legitimate and medically necessary and authorized payment of all of his Subsys claims.

[3] The allegation that Dr. Baddick signed the prior authorization forms is likewise patently false. Indeed, Dr. Baddick's office manager, Ms. Schoch, testified in a separate state law action related to A.P. that she signed the prior authorization form, not Dr. Baddick. See McCabe Decl. Ex. 3. Dr. Baddick's counsel brought this inaccuracy to the government's attention on August 12, 2022; however, the government refused to rectify the falsities and amend the pleadings. See id.

PRELIMINARY STATEMENT

Veiled by inflammatory references to off-label prescriptions, the theories of liability upon which the Complaint relies are not supported by any applicable laws, regulations, and/or legal precedent and, therefore, should be given no weight. First, the government's sole argument, that claims for drugs prescribed "off-label" are statutorily ineligible for coverage, and are therefore false per se, is contrary to Medicare policy and previously was rejected by multiple courts following exhaustive and rigorous analyses of the statutory scheme. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 351 n.5 (2001) (recognizing that off-label prescribing and use "often is essential to giving patients optimal medical care").

Simply put, off-label prescribing is a commonly accepted, permissible and often necessary practice in medicine. It certainly does not render claims for medications prescribed off-label as "false," and does not subject prescribers, like Dr. Baddick, to liability under the False Claims Act. At most, if an off-label prescription is deemed to not meet acceptable standards of practice for the community in which a physician treats patients, the prescriber may be found liable for malpractice if the patient sustained an injury as a result of same.

Furthermore, the government, in its Complaint, does not deny that Dr. Baddick's patients suffered from many severe and debilitating conditions requiring pain management and control. Indeed, the Complaint outlines that Dr. Baddick's

patients for whom he prescribed Subsys were diagnosed with serious ailments, including, but not limited to, chronic pain syndrome, degenerative disc disease, sarcoidosis, and endometriosis. Most notably, the government's Complaint does not allege that the prescription of a powerful pain medication, such as Subsys, to manage such serious conditions is generally considered unreasonable or medically unnecessary within the medical profession.

Furthermore, the government does not allege Dr. Baddick was paid by Insys (the manufacturer of Subsys) nor that he was motivated by monetary gain or any sham financial kickback arrangements to prescribe Subsys, nor that he was not enrolled in the TIRF REMS Access Program, a necessary prerequisite for all healthcare professionals prescribing Subsys. Indeed, the government concedes in its Complaint that Dr. Baddick was a trained medical doctor with decades of experience, not an Insys speaker, and properly enrolled in the TIRF REMSS Access Program prior to writing any Subsys prescriptions.

Accordingly, Dr. Baddick's prescriptions of Subsys, a potent pain medication, to treat severe and often incapacitating pain conditions, was clearly for a legitimate medical purpose within the usual course of professional practice, and the Complaint lacks any allegations to the contrary. Therefore, all of the Subsys prescriptions Dr. Baddick wrote for patients M.G. and A.P. were valid and lawful prescriptions as a matter of law, and the Complaint fails to plausibly allege otherwise.

In a transparent attempt to avoid the disposition required here – outright dismissal of all claims – the government alleges, through recitation of irrelevant statutory language, that Dr. Baddick's Subsys prescriptions were issued "under circumstances that were not for a legitimate medical purpose in the usual course of professional practice," without articulating a basis for same or even a single example of one such circumstance. See Compl. at ¶ 73. These conclusory allegations, untethered to any of Dr. Baddick's professional conduct necessarily fail, particularly in light of the government's heightened pleading obligations under F.R.C.P. 9(b).

Finally, even if any of the government's claims were plausible and legally viable (which Dr. Baddick submits they are not), they are time-barred. Accordingly, the government's lawsuit is not only substantively without merit but also procedurally improper. For the foregoing reasons, Dr. Baddick respectfully requests that the Complaint be dismissed in its entirety, with prejudice, and that Dr. Baddick be awarded costs and attorneys' fees.

I. Payors' Prior Authorization Requirements

Given the extensive off-label use of TIRF products, such as Subsys, and their significant cost, insurers, including government payors, implemented procedures to control the utilization of these drugs. The criminal Information to which the manufacturer of Subsys (Insys Pharma, Inc.), entered a guilty plea, explains:

> Insurers and their agents, including pharmacy benefit managers or PBMs (hereinafter 'insurers') controlled the costs of prescription drugs

> by requiring, among other things, prior authorizations. While their specific requirements varied, almost all insurers required patients to obtain prior authorization before agreeing to pay for a Subsys prescription. In such cases, insurers would not authorize payment if the prescription was written in exchange for a bribe, or kickback, and was not medically necessary. In general, patients had to have a specific medical diagnosis before the insurer, including Medicare, would authorize payment for Subsys. Many insurers would not pay for Subsys until the patient had tried and failed certain other preferred medications.

See McCabe Decl. Ex. 5, ¶ 7; see also id. Ex. 6, ¶¶ 147-51 (emphasis added). In the Complaint, the government alleges that Dr. Baddick signed the prior authorization forms (which he did not) indicating that both patient M.G. and patient A.P. were being treated for a number of conditions, . See Compl.¶¶ 77, 128. Thus, when these forms were submitted to Medicare's and TRICARE's pharmacy benefit managers ("PBMs") for pre-authorization of Subsys for patients M.G. and A.P., the government, thought its agents, was put on notice and made aware that Dr. Baddick was prescribing Subsys for off-label indications. Not only was the government on notice that Dr. Baddick prescribed Subsys to M.G. and A.P. for conditions other than cancer (and including cancer for A.P., as per her representation), both Medicare and TRICARE determined that Dr. Baddick's Subsys prescriptions were valid and medically necessary, and thereafter authorized payment of the pharmacies' claims for the off-label Subsys prescriptions and continuously paid the pharmacies' claims for Subsys prescriptions written by Dr. Baddick. Id. at ¶¶ 89, 92, 95, 99, 102, 105, 108, 115, 129, 132, 135, 138, 141, 144, 155. Because all of the Subsys prescriptions

were preauthorized by the government payors, had they had any indicia that Dr. Baddick's Subsys prescriptions to M.G. and A.P. were not medically necessary and/or were not issued in the legitimate course of treatment, the government would not have authorized payment for same.

II. Prescription Dispensing Event (PDE) Records

As outlined in the Complaint, when a pharmacy dispenses drugs to a Medicare beneficiary, such as patient M.G., it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event (PDE) record. See McCabe Decl. Ex. 7, at 6 ("The PDE record contains prescription drug cost and payment data that will enable CMS to make payment to plans and otherwise administer the Part D benefit."). The PDE contains a total of 37 data elements, including 17 data elements defined by CMS for purposes of administering Medicare Part D; 15 data elements from the billing transaction; and five data elements from the billing response transaction. See id. at 9; see also id. Ex. 8, at Appendix A.

Notably, PDE records do not contain any information regarding the diagnoses for which the medication was prescribed. This is because pharmacies are not provided information regarding patients' diagnoses in the ordinary course, and

diagnosis information is not required for PDE claims submissions. Among other reasons, "CMS does not have the statutory authority to require physicians to include diagnosis information on prescriptions, which are generally governed by state law." Id. Ex. 9, at 1. Thus, "diagnosis information is not a required data element on pharmacy billing transactions nor is it generally included on prescriptions. Id. Ex. 10, at 2.

As such, PDE data submitted to Medicare, as long as it is accurate and the medication that is listed was the medication dispensed, contains complete and truthful information regardless of whether the prescription drugs listed therein were prescribed for off-label indications. Therefore, patient M.G.'s PDE data, contrary to the government's conclusory assertion in the Complaint, could not have been rendered inaccurate and/or false simply because of the off-label indication for which it was prescribed.

LEGAL ARGUMENT

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides for the dismissal of complaints that fail to state a claim upon which relief may be granted. See Fed. R. Civ. P. 12(b)(6). When ruling on a dismissal motion, the Court, in addition to reviewing the facts contained in the complaint, may also consider "matters of public record, orders, exhibits attached to the complaint and items appearing in the record of the case." Pension Benefit Guar. Corp. v. White Consol.

Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).

To withstand a motion to dismiss for failure to state a claim, a complaint must do more than allege the plaintiff's entitlement to relief. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009). Indeed, to survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Accordingly, pleadings must be "more than labels and conclusions, and formulaic recitation of a cause of action's elements will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). Therefore, well-pled allegations in the complaint must be accepted as true, however, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements will not suffice." See Ashcroft v. Iqbal 556 U.S. 662, 678 (2009). The Court need not "accept unsupported conclusions and unwarranted inferences, or a legal conclusion couched as a factual allegation." Castleberry v. STI Grp., 863 F.3d 259, 263 (3d Cir. 2017); see also In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429–30 (3d Cir. 1997) (holding that a court need not credit either bald assertions or legal conclusions in a complaint when deciding a motion to dismiss for failure to state a claim). As discussed at greater length below, well-pled allegations of fraud, including those under the FCA, are subject to a substantially heightened standard of specificity as compared to non-fraud-based-claims. See F.C.R.P. 9(b).

A statute of limitations defense is among those that may be raised pursuant to Rule 12 (b)(6). Gleeson v. Prevoznik, 253 Fed. Appx. 176, 179 (3rd Cir. 2007) (citing Robinson v. Johnson, 313 F3d 128, 135-136 (3rd Cir. 2000)) In this Circuit, such a defense may be raised by a 12(b)(6) motion if "the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations. Weiss v. Bank of Am. Corp., 153 F. Supp. 3d 831, 838 (W.D. Pa. 2015). Therefore, dismissal under Rule 12(b)(6) for statute of limitations is proper "where the complaint facially shows noncompliance with the limitations period and the affirmative defense clearly appears on the face of the pleading. Id. (citing Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1390 (3d Cir. 1994), overruled in irrelevant part by Rotkiske v. Klemm, 890 F.3d 422, 428 (3d Cir. 2018) (en banc)). Similarly, a complaint can also be dismissed as time-barred "if it is plain on the face of the complaint that the limitations period cannot be tolled" or if plaintiffs fail to "plead the applicability of the [tolling] doctrine." Id. (citing Menichino v. Citibank, N.A., 2013 WL 3802451, *6–7 (W.D.Pa. July 19, 2013) (citing In re Cmty. Bank of N. Virginia, 622 F.3d 275, 301 (3d Cir. 2010), as amended (Oct. 20, 2010).

I. The Case is Time-Barred

Generally, the defense of the statute of limitations is an affirmative one, which must be pleaded in the Answer to the Complaint. However, where, as here, the

Complaint on its face demonstrates an "insuperable barrier to recovery by the Plaintiff," dismissal under Rule 12 (b)(6) is appropriate. Banks v. Schutter, 2008 WL 4826285, *4 (E.D. Pa. 2008) (citing Flight Systems. Inc. v. Elec. Data Systems Corp., 112 F3d 124, 127 (3rd Cir. 1997).

A civil action pursuant to the False Claims Act ("FCA") must be brought within six (6) years of the violation or within three (3) years of the date when the government learned or should have learned the facts material to the violation, whichever is later. See 31 U.S.C.A. §§ 3729(b)(1), (2). In no event may an action be brought after ten years of a violation. Id.

An application for payment, rather than payment of the claim, triggers the accrual of an action. U.S. ex rel. Bauchwitz v. Holloman, 671 F. Supp. 2d 674, 686 (E.D. Pa. 2009). As the Bauchwitz Court explained, liability arises from the use of fraudulent submissions intended to cause the government to issue payment. Id. The statute does not fix liability on the receipt of payment, and payment is not a prerequisite to liability. Id. In other words, liability under the FCA begins with the false statement that is intended to induce payment. Id. (citing United States v. Neifert–White Co., 390 U.S. 228, 230, 88 S.Ct. 959, 19 L.Ed.2d 1061 (1968).

a. FCA

The government alleges that on April 1, 2015, Dr. Baddick first prescribed Subsys to patient M.G., which was filled on April 1, 2015, the same day the

pharmacy submitted a claim to Medicare Part D for reimbursement of same. See Compl. at ¶¶ 78, 79. Thereafter, on April 2, 2015, Dr. Baddick signed an Insys Reimbursement Center and Patient Authorization & Referral Form indicating that M.G. had been diagnosed with degeneration of cervical intervertebral disc/degeneration of cervicothoracic intervertebral disc, chronic pain and chronic pain syndrome. Id. at ¶ 77 The form did not indicate that M.G. was diagnosed with cancer. See id. Importantly, M.G.'s last Subsys prescription was filled by the pharmacy on December 1, 2015, and the pharmacy submitted a claim to Medicare Part D for reimbursement on the same day. Id. at ¶¶107, 108.

Therefore, under § 3729(b)(1), causes of action outlined in the Complaint began to accrue on April 1, 2015, and no later than December 1, 2015, and the government had until April 1, 2021 or at the very latest, December 1, 2021 to file the instant Complaint, which was not filed until April 6, 2022 – over four (4) months after the six-year statute of limitations had expired. Similarly, under § 3729(b)(2), the facts material to the right of action were known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances on April 1, 2015, when the claim was submitted, or at the latest on April 2, 2015, when the signed Subsys Patient Authorization & Referral From indicating that M.G. had been prescribed Subsys to treat conditions other than breakthrough cancer pain was submitted. This form would have been submitted for

review to Medicare to obtain pre-approval for Subsys prescription claims providing notice to the government the exact indications for which Dr. Baddick was issuing the Subsys prescriptions at issue. As such, under the period of limitations set forth in § 3729(b)(2), the government would have had only until April 2, 2018 to file the instant Complaint. Because this is limitations period under which the government would have had the most amount of time to bring the claim, § 3729(b)(1) is the relevant statutory period applicable to the instant action. Thus, the three-year statutory period expired no later than April 2, 2018, and the six-year statutory period, as it relates to patient M.G., expired no later than December 1, 2021.

Similarly, patient A.P.'s first Subsys claim was submitted for reimbursement to TRICARE on June 11, 2015, and the last Subsys claim was submitted for reimbursement to TRICARE on October 27, 2015. Compl. at ¶¶ 129, 147, 155. On June 11, 2015, the signed Insys Reimbursement Center and Patient Authorization & Referral Form indicating that A.P. had been diagnosed with cancer, sarcoidosis, chronic pain, chronic pain syndrome, and endometriosis, was submitted. See id. at ¶ 128. Applying the same statute of limitations analysis, the relevant statutory period applicable to the instant action, as it relates to patient A.P., would have expired, at the latest, on October 27, 2021.

b. Common-law

The government also puts forth a common law theory of payment by mistake

of fact as a basis for liability. As outlined in more detail below, this theory of liability is inapplicable to Dr. Baddick as he is not the recipient of the payment, and therefore warrants dismissal as a matter of law. See Gilberton Fuels v. Philadelphia & Reading Coal & Iron Co., 342 Pa. 192, 196 (1941) ("general rule in [Pennsylvania] is, when one makes a payment under a mistake of fact, he may recover back the amount of such payment. . . . provided the recovery is demanded from the actual recipient..."). However, even if the payment by mistake theory of liability was applicable to Dr. Baddick in the instant case, the common law theory of payment by mistake of fact sounds in contract, and is therefore subject to a four-year statute of limitations period from the date of payment which would have expired in December of 2019 at the very latest. See 42 Pa. C.S.A. § 5525 (Pennsylvania applies a four-year statute of limitations for breach of contract actions.").

c. Invalid Tolling Agreement

The Complaint is devoid of any allegations relating to the government's entitlement to tolling, much less allegations containing 'sufficient factual matter' to allow the court 'to draw the reasonable inference' that discovery will show that the plaintiff's untimely claim is entitled to tolling." See Weiss v. Bank of Am. Corp., 153 F. Supp. 3d 831 (W.D. Pa. 2015) (citing Menichino v. Citibank, N.A., 2013 WL 3802451, *6–7 (W.D.Pa. July 19, 2013); In re Comm. Bank of N. Va., 622 F.3d 275, 301 (3d Cir.2010); Ashcroft v. Iqbal 556 U.S. 662, 678, (2009)). As such, the

government's Complaint should be dismissed with prejudice in its entirety as it is untimely, and all claims are barred by the statute of limitations.

Further, while there was, in fact, a tolling agreement, that agreement, signed by Dr. Baddick's previous attorney, even if had that been plead in the Complaint, it would not save the government's claims, as the agreement is invalid on its face, and therefore did not effectively toll the statutory period. Indeed, the tolling agreement is null and void because it lacks consideration. See Blair v. Scott Specialty Gases, 283 F.3d 595, 603 (3d Cir. 2002) (citing Channel Home Centers, Div. of Grace Retail Corp. v. Grossman, 795 F.2d 291, 298-299 (3d Cir. 1986)) ("Without consideration, a contract is unenforceable"). The agreement states that in consideration for Dr. Baddick signing the agreement, the government will not initiate legal action against Dr. Baddick before October of 2020. However, the tolling agreement was signed in February of 2021 rendering the consideration outlined therein of no value to Dr. Baddick, as the period during which no action would be brought against Dr. Baddick expired before the agreement was ever signed. See McCabe Decl. Ex. 4.

II. The Case is Substantively Meritless

a. The Government Has Pled No Facts Establishing that Dr. Baddick Prescribed "Not for a Legitimate Medical Purpose" and Outside "the Usual Course of Professional Practice[.]"

At various points throughout its pleading, the government repeats a refrain that is entirely conclusory: the Subsys "prescriptions were not issued for a legitimate

medical purpose by Dr. Baddick acting in the usual course of professional practice." Compl., ¶ 159. As the Third Circuit has instructed, to establish this theory, the government is obligated to prove that the prescriber "stepped outside his role as a doctor and became a criminal drug pusher." See United States v. McIver, 470 F.3d 550, 564–65 (4th Cir. 2006). Indeed, it is not sufficient to allege that a physician intentionally distributed drugs but that he intentionally "acted as a pusher rather than a medical professional. See United States v. Kohli, 847 F.3d 483, 490 (7th Cir. 2017).

Instead, in the instant Complaint, the government erroneously alleges that prescriptions issued for off-label indications can never be issued in the usual course of professional practice and/or for a legitimate medical purpose and are there not medically necessary, and thus any prescription for an off-label indication cannot be a valid prescription under Pennsylvania law. See Compl. at ¶¶ 73, 116, 156. These arguments are nothing more than bold assertions not based on relevant facts or applicable law. Indeed, off-label prescribing is a legitimate medical practice commonly accepted and encouraged by the medical community, the FDA, and insurance payors including government payors such as Medicare and TRICARE.

Therefore, prescriptions issued for off-label indications, such as Dr. Baddick's Subsys prescriptions at issue, are deemed to be valid prescriptions issued for a legitimate medical purpose in the usual course of a treating physician's practice.

Importantly, the government fails to set forth any allegations that Dr. Baddick's prescriptions are illegitimate because acted in bad faith and/or had a motive, financial or otherwise, to issue the Subsys prescriptions at issue, or that it was his practice to do so. Similarly, there are no facts and/or allegations that highlight as to why Dr. Baddick's prescribing of Subsys was not medically necessary.

To the contrary, the Complaint sets forth facts that demonstrate the Dr. Baddick examined each of the patients, made the determination to prescribe Subsys based on their medical histories and complaints of chronic pain, had monthly follow-up visits and medication checks with each patient and promptly discontinued Subsys when the circumstances necessitate it.

By way of example, the Complaint highlights M.G. and A.P., were both diagnosed with a great number of very serious and debilitating medical conditions. Id. at ¶¶ 76, 77, 125, 128. The Complaint further states that following his initial Subsys prescription to M.G. and A.P., Dr. Baddick had monthly follow-up appointments with both patients where he meticulously tracked and recorded their progress and addressed their concerns regarding Subsys. Id. at ¶¶ 80-114, 133-151.

As such, there is nothing in the record that would indicate that Dr. Baddick's Subsys prescriptions lacked medical necessity, and/or that he was acting outside the scope of legitimate medical practice that would potentially render his prescriptions medically unnecessary and/or invalid. Because the Complaint lacks any plausible

allegations that could render Dr. Baddick's Subsys prescriptions invalid, there is nothing to substantiate that Dr. Baddick caused false claims to be submitted in violation of the False Claims Act. Accordingly, the Complaint should be dismissed in its entirety.

b. The Government Has Pled No Facts Establishing that Dr. Baddick's Prescriptions Lacked Medical Necessity

As a threshold matter, off-label prescribing practices are legitimate and necessary in the practice of medicine and cannot automatically be deemed as lacking medical necessity. Indeed, "the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties." Wash. Legal Foundation v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2000). Doctors are obligated to exercise their independent medical judgment to prescribe the medicines they believe to be appropriate to treat any condition or symptom, regardless of whether the condition or symptom is covered by the FDA-approved labeling for the prescribed medicine.[4] See, e.g., West v. Atkins, 487 U.S. 42, 51 (1988) (doctor has duty to exercise "independent medical judgment" when prescribing medicine); Aaron v. Wyeth, No. 2:07-cv-927, 2010 WL 653984, at *8 (W.D. Pa. Feb. 19, 2010) ("The physician, acting as the 'learned intermediary'

[4] That authority is, of course, not unfettered under the law. See, e.g., United States v. Caronia, 703 F.3d 149, 168 n.11 (2d Cir. 2012) ("Physicians and pharmaceutical manufacturers can be held accountable for off-label drug use through medical malpractice and negligence theories of liability.").

between the manufacturer and consumer, has a duty to use the information obtained from the manufacturer, as well as his independent medical judgment . . . and weighing that knowledge against the personal medical history of the patient, to determine whether to prescribe a given drug").

The government's argument, that claims for drugs prescribed "off-label" are medically unnecessary and therefore statutorily ineligible for coverage, is contrary to Medicare policy and previously was rejected by multiple courts following exhaustive and rigorous analyses of the statutory scheme. See, e.g., Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 351 n.5 (2001) (recognizing that off-label prescribing and use "often is essential to giving patients optimal medical care"); In re Schering-Plough Corp. III, 678 F.3d 235, 239-40 (3d Cir. 2012) ("Prescription drugs frequently have therapeutic uses other than their FDA-approved indications."). While drug manufacturers are prohibited from promoting "off-label," it is not only lawful, but desirable, for doctors like Dr. Baddick to prescribe off-label. See, Carson v. Depuy Spine, Inc., 365 F. App'x 812, 815 (9th Cir. 2010) (emphasis added).

As the U.S. Supreme Court has observed, "off-label use is generally accepted," and "once a drug product has been approved for marketing, a physician may prescribe it for uses or in treatment regimes of patient populations that are not included in approved labeling." Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 350-51 & n.5 (2001); accord In re Schering Plough Corp. Intron/Temodar

Consumer Class Action, 678 F.3d 235, 240 (3d Cir. 2012) (holding that "physicians may lawfully prescribe drugs for off-label uses"); United States v. Caronia, 703 F.3d 149, 153 (2d Cir. 2012) ("[o]nce FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses.").[5]

Similarly, the FDA concurs that "'unapproved' or, more precisely, 'unlabeled' uses may be appropriate and rational in certain circumstances." McCabe Decl. Ex. 11, at 5; id. at Ex. 12, at 3 ("[I]t has become clear that prescribers have found Actiq to be useful in patients without cancer pain, both in the settings of chronic non-cancer pain with episodes of breakthrough pain and other chronic painful conditions not generally associated with breakthrough pain episodes.") (emphasis added). According to the FDA, the "unapproved use of an approved drug," otherwise known as "off label" use, includes instances in which the drug is "used for a disease or medical condition that it is not approved to treat," "given in a different way," or "given in a different dose," i.e., approved at one dose but prescribed at a different, higher dose. Id. Ex. 13; Buckman, 531 U.S. at 350 ("off-label" use is the use of a particular drug "for some other purpose than that for which

[5] See also Green & Schultz, Tort Law Deference to FDA Regulation of Medical Devices, 88 Geo. L.J. 2119, 2133 (2000) ("Physicians may prescribe drugs and devices for off-label uses"); Beck & Azari, FDA, Off–Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L.J. 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize").

it has been approved by the FDA.'").

The Complaint does not set forth one plausible allegation as to why Dr. Baddick's Subsys prescriptions can potentially be considered medically unnecessary on their face. Indeed, the government failed to allege the "date, time and place of the alleged fraud or otherwise inject precision or some measure[,]" as required by Rule 9(b) to substantiate its conclusory allegation that Dr. Baddick's prescriptions lacked medical necessity. See Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007). Therefore, the government's blanket unsupported assertions that the prescriptions lacked medical necessity are insufficient to survive dismissal.

c. The Government Has Failed to Plead "Falsity" with the Particularity Required of Rule 9(b) Because Off-Label Claims are Not False

To survive dismissal under Rule 12(b)(6), a complaint alleging that a defendant violated the FCA must, at the very minimum, include allegations that the claims submitted were indeed false. Moreover, because False Claims Act ("FCA") claims allege fraud, they are subject to the heightened pleading standard set forth in Federal Rule of Civil Procedure 9(b). United States ex rel. Petras v. Simparel, Inc., 857 F.3d 497, 502 (3d Cir. 2017); see also Frederico v. Home Depot, 507 F.3d 188, 202–03 (3d Cir. 2007), Universal Health Servs., Inc. v. United States ex rel Escobar, 136 S. Ct. 1989, 2004 n.6 (2016) (holding that Rule 9(b) applies to FCA allegations).

Rule 9(b) mandates that a party alleging fraud or mistake "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

Its purpose is to notify defendants "of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of...fraudulent behavior." Smith v. Carolina Med. Ctr., 274 F.Supp.3d 300, 308 (E.D. Pa. 2017). Describing a mere opportunity for fraud will not suffice to satisfy heightened pleading requirements; sufficient facts to establish a plausible ground for relief must be alleged. Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 157–58 (3d Cir. 2014). Specifically, the plaintiff must plead or allege the "date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007) (citing Lum v. Bank of America, 361 F.3d 217, 224 (3d Cir. 2004)).

Here, the Complaint must be dismissed because it fails to satisfy either of the necessary requirements. It does not identify a single false claim, it does not allege details how any of the claims could potentially be false, and it lacks any allegations of a scheme to submit false claims for financial gain. As such, these incurable defects require dismissal of the FCA claims in Counts 1 through 4, as well as the common-law claim in Counts 5, which is based on substantially the same allegations as the FCA claims.

d. The Government has failed to allege the presentment or submission of a false claim.

To plead a violation of the presentment or false-record-or-statement, provisions of the FCA, a complaint must allege the submission or presentment of a

false claim. See United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304–05 (3d Cir. 2011) (elements of § 3729(a)(1)(A) violation include that "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent"). This is because "[e]vidence of an actual false claim is 'the sine qua non of a False Claims Act violation.'" United States ex rel. Booker v. Pfizer, Inc., 847 F.3d 52, 57 (1st Cir. 2017). Indeed, "to trigger liability under the Act, a claim actually must have been submitted to the federal government for reimbursement, resulting in a call upon the government fisc." United States ex rel. Nathan v. Takeda Pharms. N. A., Inc., 707 F.3d 451, 454 (4th Cir. 2013) (citation omitted); United States ex rel. Nudelman v. Int'l Rehab. Assocs., Inc., No. 00-cv-1837, 2006 WL 925035, at *13 (E.D. Pa. Apr. 4, 2006) ("In other words the False Claims Act at least requires the presence of a claim, a call upon the government fisc, for liability to attach.").

Furthermore, a plaintiff must also show that the defendant made or used (or caused someone else to be used) a false record to cause a false claim to be paid or approved." United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004); see also United States ex rel. Schumann v. Astrazeneca Pharm. L.P., 769 F.3d 837, 840 (3d Cir. 2014) ("[T]he FCA makes it unlawful to knowingly submit a fraudulent claim to the government.").

Here, the Complaint fails to state a viable FCA claim because it fails to allege the presentment or submission of a false claim. The Complaint's conclusory allegation that Dr. Baddick "caused to be presented false or fraudulent claims," (Compl. at ¶¶ 159, 171), is insufficient to survive dismissal because the vague and conclusory statements are insufficient to establish the submission of a false claim. See e.g., United States ex rel. Morgan v. Express Scripts, Inc., No. 2:05-cv-1714-DMC-JAD, 2013 WL 6447846, at *14 (D.N.J. Dec. 9, 2013) (allegations that the defendants "engaged in duplicate billing, overtoiling and other fraudulent practices" were "too vague and conclusory to state a plausible entitlement to relief under 12(b)(6), let alone under the more exacting requirements of Rule 9(b)") (emphasis added)), aff'd sub nom. United States v. Express Scripts, Inc., 602 F. App'x 880 (3d Cir. 2015); United States ex rel. Tahlor v. AHS Hosp. Corp., No. 2:08-cv-02042-WJM, 2013 WL 5913627, at *13 (D.N.J. Oct. 31, 2013) (dismissing claims where "allegations [we]re conclusory statements that the [defendants] billed for inpatient admissions that were not medically necessary" (emphasis added)); see also United States ex rel. Elms v. Accenture LLP, 341 F. App'x 869, 873 (4th Cir. 2009) (granting motion to dismiss where complaint provided "no detail of [ ] conclusory allegations that [defendant] engaged in fraudulent billing practices" (emphasis added)).

While the Complaint describes that Dr. Baddick wrote Subsys prescriptions

for two patients he saw on regular basis over the period of several months, and those prescriptions were filled at a pharmacy that submitted claims and received payment for same, it fails to plausibly allege and/or plead any specific facts that could lead to a strong inference that the Subsys prescriptions much less the claims for payment of those prescriptions were false. See United States ex rel. Lord v. NAPA Mgmt. Servs. Corp., No. 3:13-cv-2940, 2017 WL 5450757, at *9 (M.D. Pa. Nov. 14, 2017) (dismissing FCA claim where complaint failed to plead any specific facts that would lead to a "strong inference" of the submission of false claims).

e. The False Claims Act Applies only to Knowing and Intentional Conduct, not Negligence.

The government's attempt to repackage post-hoc complaints about Dr. Baddick's medical decision-making and judgment with respect to the care and treatment of two patients as a FCA case should be rejected. To state a claim under the FCA, it is insufficient for the government to allege, as it does here, that Dr. Baddick "prescribe[d] Subsys to his non-cancer patients" as the foundation for its claims. Compl., ¶ 68. Under the FCA, the government is obligated to articulate clear and compelling facts demonstrating that Dr. Baddick did so intentionally, knowing full well the wrongfulness of his conduct. See United States ex rel. Schumann v. Astrazeneca Pharm. L.P., 769 F.3d 837, 840 (3d Cir. 2014) ("[T]he FCA makes it unlawful to knowingly submit a fraudulent claim to the government.").

At a minimum, to adequately plead a violation of the FCA, the Complaint

must allege that each Defendants acted with the requisite scienter, which requires that a person act "knowingly" because he or she: "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i–iii). However, the FCA claims, as outlined in the instant Complaint, warrant dismissal because the Complaint fails to adequately allege this element.

While "knowledge" and "intent" may be alleged generally under Rule 9(b), the Complaint must set forth sufficient facts from which the Court may reasonably infer that each defendant acted with the requisite state of mind. United States ex rel. Alchemy Asset Servs., Inc. v. GlaxoSmithKline Consumer Healthcare, LP, No. 10-cv-680, 2011 WL 2470595, at *2 (W.D. Pa. May 3, 2011). Absent such allegations, the complaint must be dismissed. United States ex rel. Whatley v. Eastwick Coll., No. 2:13-cv-1226-WJM, 2015 WL 4487747, at *8 (D.N.J. July 23, 2015), aff'd sub nom. United States v. Eastwick Coll., 657 F. App'x 89 (3d Cir. 2016) (granting motion to dismiss where complaint "[did] not explain . . . with particularity or sufficiently allege that [the defendants] acted with the requisite scienter").

Here, the Complaint fails to allege that Dr. Baddick acted with the requisite scienter as to falsity or materiality of any claim (or even that a false claim was submitted). See Smith v. Carolina Med. Ctr., 274 F. Supp. 3d 300, 310 (E.D. Pa.

2017) (to state a claim under the FCA, the complaint "must allege sufficient facts showing each defendant . . . **acted with knowledge with respect to both the falsity and materiality of the falsehoods**.") (emphasis added).

The Complaint does not allege that Dr. Baddick knew, had reckless disregard, or deliberate ignorance that prescribing Subsys for indications other than breakthrough cancer pain was a violation of the Controlled Substances Act, and/or that it would render the prescription invalid. See, generally, Complaint. To the contrary, as conceded by the government, medical justification(s) were provided and charted for all prescriptions written or not written. See, e.g., Compl. ¶¶ 76, 80, 81, 83, 85, 87, 90, 93, 96, 97, 100, 103, 106, 109-114, 123, 125, 126, 133, 136, 139, 142, 145, 148, 151. Nor does the Complaint allege that Dr. Baddick concealed or falsified the patients' diagnoses on the preauthorization forms to ensure Subsys coverage. See generally Complaint. As such, this incurable defect in the pleadings requires dismissal of the FCA claims as well as the mistake of fact claim that is predicated on the violations of the FCA allegations.

f. The Government Failed to Plead Materiality

To state a FCA violation, the Complaint must sufficiently "plead[ ] facts to support allegations of materiality." Universal Health Servs., Inc. v. United States ex rel Escobar, 136 S. Ct. 1989, 2004 (2016) (holding that the failure to adequately plead materiality under Rules 8 and 9(b) is an appropriate basis to dismiss FCA

claims at the motion to dismiss stage). In highlighting the materiality requirement, the Supreme Court explained:

> The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

Id. at 2003 (quoting Allison Engine Co., Inc. v. United States. ex rel. Sanders, 553 U.S. 662, 672 (2008)); see also Petratos, 855 F.3d at 490 (describing Escobar as imposing a "heightened materiality standard"). To be material, the false statement must "hav[e] a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); see United States ex rel. Hill v. Univ. of Med. & Dentistry, 448 Fed. App'x. 314, 317 (3d Cir. 2011) ("Congress has ... explicitly imposed a materiality element on claims.").

Accordingly, To adequately allege that Dr. Baddick violated the FCA, the Complaint must allege, with particularity, that Dr. Baddick made misrepresentations that were material to the government's decision to pay the Subsys claims at issue. However, the Complaint fails to allege that Dr. Baddick made any misrepresentations much less a misrepresentation that was material to Medicare's

and/or TRICARE's decision to reimburse the pharmacy for Dr. Baddick's Subsys prescriptions.

To the contrary, the Complaint sets forth specific information that indicates that Dr. Baddick fully disclosed to the government payors the conditions for which he was prescribing Subsys to patients M.G. and A.P. and that, thereafter, ***the government approved via the prior authorization procedure and subsequently paid for the drugs at issue***. Thus, while the government payors were fully aware why Dr. Baddick was prescribing Subsys, they deemed those Subsys prescriptions medically necessary and preauthorized payment of the Subsys claims.

Even if some unsubstantiated theory that Dr. Baddick's prescribing of Subsys involved some type of fraudulent actions existed, which it does not, there is nothing in the Complaint that would connect that supposed fraudulent action with the payment of claims, such as his falsification of patient records to circumvent the government-conducted pre-authorization process. See United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379–80 (4th Cir. 2008) (affirming dismissal where plaintiff's failure to connect fraudulent action with payment "[did] not meet the minimum standards established by Rule 9(b)").

In this case, government payors implemented a process, referred to as "prior authorization," to make coverage determinations on Subsys claims prior to approving payment. Critically, the government concedes in its Complaint that, as

part of this determination, the off-label uses were disclosed to Medicare and TRICARE when a signed the Reimbursement Center and Patient Authorization & Referral Form was then submitted to the government payors who in turn approved the Subsys claims at issue despite the fact that the forms included diagnoses other than cancer. See Compl. at ¶¶ 77, 128.

III. The non-federal claim should be dismissed on additional grounds

A. The Government Cannot Recover from Dr. Baddick Under the Payment by Mistake of Fact Theory of Liability

An essential element of the payment by mistake of fact claims is that the defendant retained the funds—payments from Medicare and TRICARE for the Subsys prescriptions in this case. See United States ex rel. Doe v. Heart Sol., PC, 923 F.3d 308, 319 (3d Cir. 2019). Payment by mistake of fact allows the government to recover money from a defendant that "its agents have wrongfully, erroneously, or illegally paid. Id. (citing United States v. Wurts, 303 U.S. 414, 58 S. Ct. 637, 82 L. Ed. 932 (1938)). Indeed, recovery under the payment by mistake of fact theory is only allowed if "the ***defendant would be unjustly enriched*** by the retention of the plaintiff's money and, therefore, should in equity and good conscience return it." United States v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430, 451 (E.D. Pa. 2004) (emphasis supplied) (quoting Wilson & Co. v. Douredoure, 154 F.2d 442, 445 (3d Cir.1946).

Here, the government, in its Complaint, makes clear that the pharmacies

submitted claims for Dr. Baddick's Subsys prescriptions, Medicare and TRICARE paid the pharmacies for the submitted claims, and that ***the pharmacies*** received and retained those funds. See Compl. ¶¶ 79, 82, 84, 86, 89, 92, 95, 99, 102, 105, 108, 129, 132, 135, 138, 141, 147, 175. The Complaint is lacking any allegation that Dr. Baddick received any portion of payments made on the Subsys claims and/or that he retained any of those funds. Because Dr. Baddick was not the recipient of the funds the Complaint alleges were mistakenly paid to the pharmacies, he cannot be held liable under a payment by mistake theory of liability.

B. The Court is not Obligated to Maintain Jurisdiction Over the Remaining Non-Federal Cause of Action

As outlined in detail above, all of the government's claims, including the common law claim, should be dismissed because the Complaint was untimely filed and fails to state a claim for which relief can be granted. Additionally, the government's common law payment by mistake of fact claim, which is altogether inapplicable to Dr. Baddick, does not pose a federal question. As such, when the Court dismisses the FCA claims, it need not maintain jurisdiction over the remaining non-federal cause of action, giving rise to an additional bases for dismissal. See Carnegie-Mellon Univ. v. Cohill, 484 U.S. 343, 350 n.7 (1988) (citing Rosado v. Wyman, 397 U.S. 397, 403-05 (1970) as clarifying that the statement made in United Mine Workers of America v. Gibbs, 383 U.S. 715, 726 (1966), that "'if the federal claims are dismissed before trial . . . the state claims should be dismissed as well' …

simply recognizes that in the usual case in which all federal-law claims are eliminated before trial, the balance of factors will be considered under the pendent jurisdiction doctrine – judicial economy, convenience, fairness, and comity – will point toward declining to exercise jurisdiction over the remaining state-law claims"); Honeywell Int'l, Inc. v. Phillips Petroleum Co., 415 F.3d 429, 431 (5th Cir. 2005) (finding that an action must have its own basis for federal jurisdiction or must be dismissed: "It can no longer rely on the supplemental jurisdiction afforded by 28 U.S.C. § 1367(a) for there is nothing left to supplement").

Given the foregoing, Dr. Baddick respectfully requests the Court decline to exercise supplemental jurisdiction over the common law claim should it deem that outright dismissal of the federal claims is appropriate.

CONCLUSION

For the reasons identified above, the Court should dismiss the Complaint and award attorneys' fees and costs to Defendant. Because the government cannot cure the myriad of defects in the Complaint, and any amendment of the Complaint would be futile, the Court's dismissal should be with prejudice. See Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000) (leave to amend should not be granted if "the amendment would not cure the deficiency").

Dated: April 4, 2023

Respectfully submitted,

/s/ Conor R. McCabe

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CERTIFICATE OF SERVICE

I hereby certify that on this day, a true and correct copy of the foregoing has been served on all parties of record through the Court's CM/ECF system.

Dated: April 4, 2023

/s/ Conor R. McCabe
Conor R. McCabe